

GAO

United States General Accounting Office

Report to Congressional Committees

October 2000

# INTELLECTUAL PROPERTY

## Deposits of Biological Materials in Support of Certain Patent Applications



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### Abbreviations

ATCC	American Type Culture Collection
BIO	Biotechnology Industry Organization
DNA	deoxyribonucleic acid
EPO	European Patent Office
GAO	General Accounting Office
IDA	International Depository Authority
JPO	Japanese Patent Office
NRRL	Agricultural Research Service Culture Collection
PTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization



**United States General Accounting Office  
Washington, D.C. 20548**

October 16, 2000

The Honorable Orrin G. Hatch  
Chairman  
The Honorable Patrick J. Leahy  
Ranking Minority Member  
Committee on the Judiciary  
United States Senate

The Honorable Howard Coble  
Chairman  
The Honorable Howard L. Berman  
Ranking Minority Member  
Subcommittee on Courts and  
Intellectual Property  
Committee on the Judiciary  
House of Representatives

Under U.S. patent law, a patent must describe the subject invention in detail sufficient for a person skilled in the particular field to use or make it. For certain biological materials—such as seeds, fungi, viruses, and bacteria—words alone may not always be enough for a proper description. In these cases, the inventor may have to deposit a sample—referred to as a biological deposit—in a facility where it will be available to others once the patent is granted.

Some members of the U.S. biotechnology industry believe that biological deposits make patent infringement easier, reasoning that a person or organization can obtain a sample of the deposit and then reproduce the invention with minimal effort and expense. These concerns increased with the enactment of the American Inventors Protection Act of 1999,<sup>1</sup> which provides that, beginning in November 2000, a patent application filed both in the United States and another country will be published 18 months from the date of filing and be made available to the public at that time rather than at the time the patent is granted, as is now the case. The biotechnology industry fears that the earlier publication, with the public having access to the patent application, will also mean an earlier release of the biological

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<sup>1</sup>The American Inventors Protection Act of 1999 is Title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999, which itself was incorporated into the Consolidated Appropriations Act for 2000 (P.L. 106-113, enacted Nov. 29, 1999).

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deposits. In this context, the Congress mandated that we conduct a study and submit a report to the Congress on the potential risks to the U.S. biotechnology industry relating to biological deposits in support of biotechnology patents.

As agreed with your offices, the objectives of our work were to determine (1) the patent infringement risks the U.S. biotechnology industry faces as a result of biological deposits being made available to others once a patent is granted and (2) the effect the new 18-month patent publication requirement will have on these risks. For this report, these risks relate to a person or organization gaining access to a biological deposit once a patent is granted and then using the deposit as a means to infringe on the patent supported by the deposit by either transferring the deposit to third parties or exporting the deposit out of the country. Further details on our scope and methodology are included in appendix I. We also agreed to develop a historical analysis of the current biological deposit requirements generated through statute, regulation, case law, and treaty. This analysis is included in appendix II.

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## Results in Brief

The public's access to biological deposits once a patent is granted has not to date increased the risk of patent infringement for the U.S. biotechnology industry. On the basis of our review of court cases and our discussions with biotechnology industry representatives and other officials, we found no documented cases of a person or an organization having ever obtained a sample of a biological deposit and then using it to infringe on the patent. This result to date of course does not mean that no potential risk exists. To the contrary, because samples of a biological deposit can be obtained once a patent is granted, the potential exists today and will exist into the future that an individual or an organization could use the deposit to infringe the patent. To gain some perspective on the number of patents potentially at risk—since there are no comprehensive data showing the total number of patents outstanding that are supported by biological deposits—we analyzed all of the 52,841 patents the United States granted during the last 3 months of 1999. We found that 308, or about 0.6 percent, were supported by biological deposits in U.S. facilities. Furthermore, we found that patents for seeds—a field of biotechnology in which the deposit itself is seen by the seed industry as providing the “factory” for the seeds’ reproduction—represent an even smaller subset, accounting for 53 of the 308 patents.

The new 18-month publication requirement for patent applications need not have any effect on risks for patent infringement because this

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requirement does not change when biological deposits can be released to persons other than the applicant. Generally, the statute requires that patent applications be published at 18 months from the date of filing and be made available to the public at that time, unless the applicant certifies that he or she is not and will not be applying for a patent in any other country or under a multinational agreement that requires 18-month publication. However, the statute does not require an associated release of a biological deposit concurrent with 18-month publication because even though the application may refer to the biological deposit, the deposit itself is not part of the application. The required time for releasing deposits continues to be the time a patent is granted.

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## Background

A patent is a government grant giving an inventor the right to exclude others from making, using, offering to sell, selling, or importing his or her invention for a limited time. In the United States, the sole granting authority for patents is the United States Patent and Trademark Office (PTO), an agency within the Department of Commerce. PTO grants patents for an array of inventions, including those in such technical fields as microchips, software, telecommunications, and genetic research. Most patents today are granted for a term of 20 years from the date the patent application was filed.

In recent years, perhaps no field has seen a greater increase in new technology than has the field of biotechnology. Biotechnology is an area of science often defined as a combination of advances in our understanding of cellular and molecular biology; plant, animal, and human genetics; and the ability of the human immune system to fight disease. Biotechnology is a collection of technologies having numerous applications, such as manufacturing processes used in health care, food and agriculture, industrial processes, and environmental cleanup. In appendix III, we provide further information about biotechnology and the importance of the biotechnology industry to the U.S. economy.

While new products and processes created through biotechnology can be patented, applications for patents involving biological materials—such as seeds, fungi, viruses, cells, cell lines, and bacteria—present a unique challenge. Under U.S. law, a patent application must provide a description of the invention that would enable a person skilled in the particular field to use or make it. Words alone may not be sufficient to describe a biological material, however. In such cases, an applicant can satisfy the description requirement by referring in the application to biological material placed in

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an approved depository that will provide samples to requesters once the patent is granted.

Other countries also have had to deal with the issue of biological deposits. Accordingly, in an attempt to regulate biological deposits throughout the world, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty) was established in 1977 and became operational in 1981. Under this treaty, signatory countries—including the United States, which ratified the treaty in 1980—must recognize a biological deposit made in any depository approved by the World Intellectual Property Organization (WIPO). The treaty also established international standards for biological deposits and provided that a deposit in any WIPO-approved depository will be recognized as meeting the deposit requirements throughout the world. At present, there are 48 signatory nations to the Budapest Treaty and 31 depositories—known as International Depositary Authorities (IDA)—recognized by WIPO. The United States has two IDAs—the American Type Culture Collection (ATCC) in Manassas, Virginia, and the Agricultural Research Service Culture Collection (known as NRRL<sup>2</sup>) in Peoria, Illinois.

PTO issued regulations in August 1989 on the requirements for depositing biological materials for patent purposes. Appendix II provides an overview of the current requirements on biological deposits as generated through statute, regulation, case law, and treaty.

Some within the U.S. biotechnology industry believe that U.S. patents supported by biological deposits are subject to higher risks of infringement or abuse than are other patents. They note that once a patent supported by a deposit has been granted, others may obtain samples of the deposited materials and then use them for their own gain without any regard to patent rights. They also say that the patent holder may have few effective remedies since (1) reporting and tracking mechanisms are limited; (2) relief or recovery of damages may be impossible in other countries, particularly if these countries do not recognize the patentability of the materials in question; and (3) even where possible, lawsuits are difficult and expensive. In an industry in which certain inventions may require an investment of hundreds of millions of dollars and potential revenues can run into the billions, the organizations holding the U.S. patents to

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<sup>2</sup>The depository formerly was named the Northern Regional Research Laboratory and continues to be known by the former acronym.

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biotechnological inventions do not want to take these risks. They also believe they are held to a higher standard than other patent holders in the United States—who do not have to make deposits—and their counterparts in other countries—who are provided greater protection against potential misuse.

The concerns over biological deposits appear to have increased after enactment of the American Inventors Protection Act of 1999. Among other things, this act provides for PTO's publication of patent applications regarding inventions for which patent protection has been or is to be applied for in another country where 18-month publication is required. The industry is concerned that, under the new requirement, the biological deposits might become available earlier than in the past. PTO is considering whether regulations should be issued concerning the early release of biological deposits but plans no action pending issuance of our report on the subject.

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## Access to Biological Deposits Has Not Increased the Risk of Patent Infringement for the Biotechnology Industry

Fears that access to biological deposits would result in an increased risk of patent infringement within the U.S. biotechnology industry have, to date, not been realized. We were unable to identify a single case in which a person or organization had gained access to a biological deposit and then used it to infringe the underlying patent. This information does not mean, however, no potential risk exists. To the contrary, because samples of a biological deposit can be obtained once a patent is granted, the potential exists today and will exist into the future that an individual or an organization could use the deposit to infringe the patent. To put the number of patents potentially at risk in perspective—since there are no comprehensive data showing the total number of patents outstanding that are supported by biological deposits—we analyzed all of the 52,841 patents the United States granted during the last 3 months of 1999. We found that 308, or about 0.6 percent, were supported by biological deposits in the two IDAs located in the United States. We also found that patents for seeds represented an even smaller subset, accounting for 53 of the 308 patents that were supported by biological deposits.

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## No Cases of Abuse Have Been Documented

We could find no court cases where biological deposits had ever allegedly been misused to infringe on a patent. Also, since the case law might not show (1) cases that were dropped, settled, or resolved at the trial court level or (2) suspected cases of abuse that had not been litigated, we also asked knowledgeable patent attorneys; representatives from the

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biotechnology industry; and officials from PTO, ATCC, NRRL, and WIPO to refer us to known or suspected cases. None of these were able to provide a single documented instance implicating biological deposits in a case of patent infringement.

Although we found no documented cases of abuse, this does not mean that there is no potential risk that access to biological deposits could be misused. To the contrary, because samples of a biological deposit can be obtained once the patent is granted, the potential exists today and will exist into the future that an individual or an organization could use the deposit to infringe the patent.

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#### While Comprehensive Data Are Not Available, Relatively Few Patents Appear to Be Supported by Deposits

There are no comprehensive data showing the number of biotechnology patents that are supported by biological deposits and that therefore are potentially at risk. However, on the basis of our review of statistics provided by WIPO, the IDAs, and PTO, relatively few patents appear to be supported by deposits.

WIPO is the only organization that accumulates and reports statistics on biological deposits held by the 31 IDAs it has approved. However, a WIPO official told us that the organization reports only those statistics it receives. For example, WIPO's annual reports did not provide statistics for 11 IDAs in 1998 and 9 IDAs in 1997.<sup>3</sup> Also, this official said that WIPO does not validate the data or ensure that all of the 31 IDAs submit reports.

We asked each of the 31 IDAs to verify the statistics they had provided WIPO in 1997 and to provide us with new data for 1998 and 1999. As shown in appendix IV, the 27 IDAs that responded reported 39,623 biological deposits on hand at the end of calendar year 1999, compared with 36,735 at the end of 1998 and 33,318 at the end of 1997. The data do not indicate, however, how many patents are supported by these biological deposits because a single deposit may support more than one patent and a single patent may have more than one deposit.

Two of the largest IDAs are ATCC and NRRL. Together, these two U.S. depositories reported 20,461 deposits—51.6 percent of the world total—at

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<sup>3</sup>A case in point involves one of the U.S. IDAs—NRRL. In the 1997 WIPO report, NRRL was not listed, even though NRRL officials said that they had forwarded their statistics to WIPO. NRRL's data showed that it had 2,808 deposits on hand at Dec. 31, 1997.

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the end of 1999. At this same time, PTO reported that a total of 1,242,853 U.S. patents were in force.

To gain a better understanding of the relationship between patents and deposits in the United States, we analyzed all 52,841 patents granted by PTO during the last 3 months of 1999. We found that 308, or about 0.6 percent, of these patents indicated they were supported by a deposit in ATCC or NRRL. Only 1 of the 308 patents indicated that a deposit was made in both depositories.

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#### Biological Deposits Supporting Seed Patents Illustrate the Potential Risks

In our discussions with representatives from the biotechnology industry, seed company representatives expressed the view that self-replicating plant varieties are unlike other inventions, including those created by other segments of the biotechnology industry. The difference is that the seed is its own "factory" and that a person intent on infringing the patent in question merely has to obtain a sample, plant the seeds, and harvest them, all at low cost. There is no need for a laboratory or other production facilities.

The seed companies said that, while there is a concern with a person committing infringement in the United States, a more serious problem exists with the unauthorized use of the deposited material in other countries. Most other countries will not issue patents for plant varieties. Since there can be no infringement in these countries unless there is a recognized patent, suing someone for patent infringement would be impossible. Even if such suits were possible, they would be expensive, and the seed companies would have a difficult time showing that the seeds were replicated or were derived from the sample of the biological deposit in question.<sup>4</sup>

One seed company representative acknowledged that seeds of self-replicating plant varieties could be obtained from the market place and misused without having to rely on accessing the deposited material. However, this representative noted that hybrid seeds generally thought to be immune from reverse engineering would still be at risk because the

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<sup>4</sup>See *Biotechnology: Information on Prices of Genetically Modified Seeds in the United States and Argentina* (GAO/RCED/NSIAD-00-55, Jan. 21, 2000). This report discusses related issues, such as the protection a U.S. seed company has for a seed patented in the United States that has not received patent protection in Argentina.

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seeds of the parental lines used to make the hybrid are often deposited to enable the patent on the hybrid or on the parental line *per se*.

We could not determine how many of the biological deposits outstanding worldwide involved seeds because no database provides this information. According to WIPO, however, only 4 of the 31 approved IDAs even accept seeds. As shown in appendix IV, these include ATCC, and one IDA each in England, Japan, and China.

We asked ATCC to estimate the number of seed deposits on hand. ATCC estimated that less than 8 percent of its deposits for patents were for seeds. Also, during our review of patents issued by PTO during the last 3 months of 1999, we identified 53 seed patents for which a deposit had been made in ATCC. While these represented only 0.1 percent of all 52,841 patents issued during the period, they accounted for 17.2 percent of the 308 patents for which a deposit had been made at one of the two U.S. depositories.

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## The 18-Month Publication Requirement Need Not Affect the Release of Biological Deposits

The 18-month publication requirement, which goes into effect on November 29, 2000, need not have any effect on the risks for patent infringement because this requirement does not change when biological deposits can be released to persons other than the applicant. The statute generally requires that patent applications be published at 18 months from the date of filing and be available to the public at that time unless certain conditions exist. For example, applicants can avoid 18-month publication by certifying their intent to forgo applying for patents in any country or under a multinational agreement that requires 18-month publication. However, the statute does not require the release of a biological deposit that an application refers to but that is neither part of the application nor within PTO's custody or control.

While Europe<sup>5</sup> and Japan currently have 18-month publication requirements for their patents, they also have requirements that restrict the release of biological deposits. Thus, patent owners are provided with greater protection against infringement. Some within the biotechnology industry would like to see the United States adopt some of these protections in any future legislative action on this front.

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<sup>5</sup>“Europe” as used in this report refers to the 19 countries that are members of the European Patent Organization.

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### The Law Does Not Require the Release of Deposits at 18-Month Publication

One concern of the biotechnology industry is that the new 18-month publication requirement for patent applications could result in the earlier release of biological deposits. It notes that deposits currently are available at publication, which is concurrent with issuance of the patent. If the deposits are released with the application at 18 months under the new requirement, the biotechnology industry believes that deposits in the future would be available sooner because PTO typically takes more than 18 months to examine biotechnology patent applications.

Our analysis of U.S. patents issued during the last 3 months of 1999 supports the biotechnology industry's view that most patents requiring deposits take longer than 18 months to issue. As shown in appendix V, for those 308 patents that were issued during the last 3 months of 1999 indicating that a deposit had been made with ATCC or NRRL, the average examination time, which PTO refers to as "pendency," was 36.9 months.<sup>6</sup> The average examination time for seed patents—22.6 months—was considerably lower.

On the basis of these statistics, it does appear that applications supported by biological deposits generally will be published earlier under the new law. This does not mean, however, that the deposits will be available earlier. To the contrary, we find no requirement that a biological deposit be released at 18 months concurrent with publication of the application. In our discussions with PTO officials, they noted that the law does not permit any specific changes regarding the release of biological deposits until after this report is issued. They said that deposits would continue to be available only after the patent is granted unless PTO changes its regulations to require earlier release. They said that they did not know if they would require the release of deposits at 18 months but, at any rate, would make no changes to the regulations until after we had completed the study that is the basis for this report.

We agree that PTO is not required to make any changes to the regulations requiring the release of biological deposits concurrent with 18-month publication. As amended, 35 U.S.C. § 122 requires only that "each application for a patent shall be published, in accordance with procedures determined by the Director, promptly after the expiration of a period of 18 months from the earliest filing date for which a benefit is sought.... ." In its

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<sup>6</sup>PTO defines "pendency" as the period from the date when an application is filed until the date when a patent is issued or the application is abandoned.

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use of the term "application," the law refers in context to 35 U.S.C. § 111, which provides that an application for a patent is to include

"(A) a specification as prescribed by section 112 of this title; (B) a drawing as prescribed by section 113 of this title; and (C) an oath by the applicant as prescribed by section 115 of this title. ... The application must be accompanied by the fee required by law. The fee and oath may be submitted after the specification and any required drawing are submitted...."

A specification in the patent may refer to a biological deposit; however, the law does not require that the deposit itself be submitted with the application. Thus, even if the application is published at 18 months, the biological deposit does not have to be released until the patent is granted. The only effect on the deposit is that the publication will notify others of the existence and location of the deposit earlier than would have been the case previously.

PTO exercises limited control over deposits and no control over depositories. The courts have held that deposits need not be publicly released until the issuance of the patent. In the face of these decisions, PTO may wish to seek specific legislation if existing practices are to be changed.

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**An Application Does Not Have to Be Published at 18 Months if There Is No Foreign Filing**

A patent applicant could avoid 18-month publication by choosing not to file applications in other countries. The law requiring 18-month publication specifically exempts those applications filed only in the United States, provided that the applicant certifies that he or she is not going to file an application in any country or under a multinational agreement that requires 18-month publication.

This provision would appear to be of particular benefit for patent applications involving seeds, an area of concern regarding potential abuse of biological deposits. PTO officials said that most countries do not recognize the patentability of seeds. Thus, there may be less incentive to seek foreign filing, and the seed companies can avoid 18-month publication entirely by filing only in the United States.

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**Europe and Japan Have Protections Not Available in the United States**

Patents issued by the European Patent Office (EPO) and the Japanese Patent Office (JPO) already are subject to 18-month publication requirements, with EPO providing that samples of biological deposits are available at that same time. In addition, both of these patent offices offer protections for biological deposits that are not available on patent

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applications in the United States. Information provided by EPO and JPO and discussions with patent attorneys and representatives of the biotechnology industry indicate that 18-month publication has not caused problems related to the potential misuse of biological deposits in Europe or Japan.

In Europe, a sample from the deposit is available at the time the patent application is published; however, the depositor can stipulate that the sample is available only to an expert approved by either EPO or the depositor. Also, the sample can be used only for experiments and testing purposes, cannot be transferred to other parties, and can be obtained only after a formal request is made through EPO.

In Japan, the patent application is also published 18 months from the date of filing. However, a sample is not available at that time. At the end of the examination period, the application is granted and published for a second time, after which there is a 6-month "opposition period." Samples from a biological deposit can be released after the second publication. As in Europe, a request must be made through JPO, and the recipient is precluded from using the sample for any purpose other than testing and research. Also, the sample cannot be transferred to other parties. Unlike in Europe, samples in Japan do not have to be released to an expert.

To determine whether we could draw any correlations between requirements for the release of biological deposits and the actual numbers of samples released, we reviewed data provided by WIPO and the IDAs on samples released by the world's 31 approved IDAs in 1999. We found that, as shown in appendix IV, ATCC was by far the leader, with an estimated 7,000, or 95 percent, of the samples released to parties legally entitled worldwide during the year. NRRL accounted for another 123 releases. Conversely, the IDAs in Europe released 190 samples and the IDA in Japan released 63 samples, together accounting for less than 4 percent of the world's total.

Representatives from the U.S. biotechnology industry told us that they believe that these numbers provide evidence that deposits are too easily obtained and subject to less control in the United States. They also believe that the controls placed over biological deposits in Europe and Japan offer greater protection for patent holders than do those in the United States. They said they would like to see similar controls placed over deposits in this country, particularly if deposits are to be released concurrent with 18-month publication of the patent applications.

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## Agency Comments

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We provided a draft of this report to PTO for its review and comment. PTO generally made favorable comments about the report. Consistent with our report's findings, PTO stated that the Patent Act requires applicants to describe the claimed invention in sufficient detail to enable a person of skill in the art to practice the invention and that this requirement governs all inventions from the simplest mechanical inventions to the most sophisticated biological inventions. It also agreed with our finding that very few applications actually take advantage of the opportunity to use a deposit to fulfill the disclosure requirement. PTO added that the ability to submit a deposit enables American inventors to seek patent protection for their inventions where patent protection might not otherwise be available due to constraints imposed by merely using words to describe the invention. PTO concluded that while this system is not unique to the United States, this ability has contributed to the United States biotechnology industry being a world leader in that field.

The full text of PTO's comments is included in appendix VI.

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We performed our review between February and October 2000 in accordance with generally accepted government auditing standards.

We are sending copies of this report to Senator Judd Gregg, Chairman, Subcommittee on Commerce, Justice, State, and the Judiciary, Committee on Appropriations; Senator Ernest F. Hollings, Ranking Minority Member, Subcommittee on Commerce, Justice, State, and the Judiciary, Committee on Appropriations; Representative Henry J. Hyde, Chairman, Committee on the Judiciary; Representative John Conyers, Jr., Ranking Minority Member, Committee on the Judiciary; Representative Harold Rogers, Chairman, Subcommittee on Commerce, Justice, State, the Judiciary, and Related Agencies, Committee on Appropriations; Representative Jose E. Serrano, Ranking Minority Member, Subcommittee on Commerce, Justice, State, the Judiciary, and Related Agencies, Committee on Appropriations; the Honorable Norman Y. Mineta, Secretary of Commerce; the Honorable Jacob J. Lew, Director, Office of Management and Budget; and the Honorable Q. Todd Dickinson, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office. We will also make copies available to others on request.

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If you or your staff have any questions or need additional information, please call me at (202) 512-3841. The key contributors to this report are listed in appendix VII.

A handwritten signature in black ink, appearing to read "Gary L. Jones".

(Ms.) Gary L. Jones  
Director, Natural Resources and  
Environment

# Scope and Methodology

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The American Inventors Protection Act of 1999 mandated that we conduct a study and submit a report to the Congress on the potential risks to the U.S. biotechnology industry relating to biological deposits in support of biotechnology patents. We agreed with the congressional committees that the objectives of our work would be to determine (1) the patent infringement risks the U.S. biotechnology industry faces as a result of biological deposits being made available to others once a patent is granted and (2) the effect the new 18-month patent publication requirement will have on these risks. For purposes of this report, these risks relate to a person or organization gaining access to a biological deposit once a patent is granted and then using the deposit as a means to infringe on the patent supported by the deposit by either transferring the deposit to third parties or exporting the deposit out of the country.

We focused our efforts on examining the risks of biological deposits being transferred to third parties and/or exported and on determining how the risks to the U.S. biotechnology industry would likely be affected by the new requirement that most patents be published 18 months from the date of filing and be made available to the public at that time rather than at the time the patent is granted. As part of our work, we developed a historical analysis of the current requirements generated through statute, regulation, case law, and treaty. We based our work on discussions with officials and documentation available from the United States Patent and Trademark Office (PTO); the American Type Culture Collection (ATCC) in Manassas, Virginia; the Agricultural Research Service Culture Collection (known as NRRL) in Peoria, Illinois; businesses and trade associations associated with the biotechnology industry; law firms specializing in patents and biotechnology; International Depositary Authorities (IDA) in other countries; the World Intellectual Property Organization (WIPO); and patent offices in Europe and Japan.

We developed our historical analysis of the current requirements by tracing their development from the time the federal courts determined that utility patents could be obtained on self-reproducing plants, through the provisions of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, through PTO's issuance of regulations, to the 1999 changes in the patent law requiring 18-month publication.

We developed, to the extent information was available, statistics on biological deposits made in IDAs and biotechnology patents examined by PTO. To provide greater information than that available from WIPO on

deposits in the 31 IDAs WIPO has approved, we contacted each of the IDAs by letter, facsimile, or e-mail. We then compared the data provided by the IDAs with the data available from WIPO. We made follow-up contacts with the IDAs to obtain additional and clarifying information when necessary. We did not otherwise validate or verify the information provided by the IDAs, however, as we had no means to do so.

To obtain further information on deposits made in the United States, we analyzed all the patents issued by PTO in October, November, and December 1999 that made reference to ATCC or NRRL. For each such patent, we determined whether, when, and where the applicant had actually made a deposit. We also obtained information on when the patent applications were filed and the patents were issued. We used this information to determine how long the applications took to issue and to compare these times with the time that would have expired had the new 18-month publication requirement been in effect. The data we accumulated are not generalizable to the universe of patents outstanding but do provide a comprehensive look at a cross-section of patents issued over a discrete period.

To compare U.S. rules on biological deposits with the rules in other countries, we developed information showing how biological deposits are handled by the patent offices in Europe and Japan, both of which already have an 18-month publication requirement and rank second and third, respectively, in the volume of patent activity after PTO. We limited our work to obtaining information that was readily available through published documents and discussions with knowledgeable personnel. We did not otherwise verify or validate the information obtained.

We performed our review between February and October 2000 in accordance with generally accepted government auditing standards.

# Historical Analysis of Biological Deposit Requirements

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To receive a patent in the United States, a product or process must be new, useful, and nonobvious. Since the U.S. Supreme Court decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), it is clear that a living organism can be patented if it is the product of human invention and does not occur naturally. This landmark decision has paved the way for a variety of U.S. patents involving living materials, including fragments of deoxyribonucleic acid (DNA).

An applicant for a patent involving biological materials must meet the same requirements as other inventions. These requirements provide for a detailed description and specification of the invention, as set out in 35 U.S.C. § 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The practice of depositing microbiological material in support of patent applications appears to have been well established by 1955, by which time it is described in the literature as being used to support applications for patents on a variety of antibiotics. "Microbiology and a Standard Format for Infra-Red Absorption Spectra in Antibiotic Patent Applications," 37 J. Pat. Off. Soc., pp. 855-859 (1955). The practice developed to meet the requirement that an application must include a specification containing a written description of the invention and of the manner and process for making and using it. 35 U.S.C. §§ 111, 112 (1994). In the terms of the statute, the specification must be

"... in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." *Id.*

The need to meet these requirements applies even if a process to be patented is based upon the use of a microorganism as "starting material," material the applicant may have a great deal of difficulty describing uniquely using words, alone. The use of biological deposits

"... arose from a consideration of how the invention could be practiced by others skilled in the art during the lifetime of the patent and after its expiration. The written description of the microorganism in the absence of its identification by the catalogue number of a recognized depository is insufficient to enable others to reproduce the functional strain with

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certainty and use the invention without involving extensive experimentation." 37 J. Pat. Off. Soc., *supra*, 856.

In *Application of Argoudelis*, 434 F.2d 1390 (1970), the Court of Customs and Patent Appeals discussed at length the problem of documenting a process patent in such cases, that is, in cases where the starting material is a microorganism. As the court stated the problem,

"... a unique aspect of using microorganisms as starting materials is that a sufficient description of how to obtain the microorganism from nature cannot be given. Such a description could only detail an experimental screening program similar to the screening programs followed in discovering the microorganism in the first instance. If the microorganism involved were of very common occurrence, it might be found in a relatively short time, but if it were not of common occurrence, it might not be found for a very long time, if found at all. The microorganism involved here, of course, was not known and available to the workers in the art since it was newly discovered by appellants." 434 F.2d at 1392.

In *Argoudelis*, the applicants sought to patent a process for producing antibiotic compounds utilizing a microbiological organism the applicants had identified. The applicants deposited cultures of the microorganism in a public depository operated by the U.S. Department of Agriculture. The deposit was made prior to filing the application, which referred to the deposit and included a detailed taxonomic description of the microorganism. At the time of the deposit, the applicants and the Department of Agriculture agreed that prior to the issuance of a patent, the deposit would be subject to rule 14 of the United States Patent Office Rules of Practice, pertaining to the public disclosure of documents and other materials filed in support of a patent application. Rule 14 provided that access would not be given to such materials without the applicants' approval, except as necessary to the proper conduct of the business before the patent office. The Board of Patent Appeals and Interferences rejected the application as deficient under 35 U.S.C. § 112 because the microorganism was not known to the public and was not made known by virtue of the deposit, which was secret and confidential.

Several incidental points are important to properly understanding and applying *Argoudelis*.

- *Streptomyces sparsogenes* var. *sparsogenes*—the material that was deposited—was not the intellectual property that the applicants sought to patent. The subject matter was a process for the manufacture of *sparesogenin* and *sparesogenin* A, antibiotics that can be produced by *streptomyces sparsogenes* var. *sparsogenes* using the applicants'

process. The *streptomyces sparsogenes* var. *sparsogenes* was a starting material used to carry out the applicants' process.

- The biological deposit occurred outside the patent office. Public access to the deposited material was to be permitted when a patent was issued.
- The making of the deposit under terms that would result in its release if the purpose for the deposit was accomplished, that is, if the patent application was approved, was a voluntary release of confidentially held information and material. The effect of placing the information and material in the public domain was to "alter the playing field," that is, to change the base of knowledge that applied to determine the patentability of the applicants' process.
- By agreeing to the planned release of the deposit, the applicants altered the capability that persons skilled in the art would have, allowing an effective demonstration as to how the applicants' invention was made and used.

Noting that under rule 14, public access would be allowed to the deposited material once a patent was issued, the *Argoude lis* court reversed the Board's decision. The court concluded that 35 U.S.C. § 112 does not require that the deposited material be available to the general public at the time the application is filed. Prior to that time, the applicant was not required to give access to the biological materials except as might be necessary to facilitate the patent office's review of his application. If the application were not issued, no deposit was required, a fact Judge Baldwin elaborated upon in his concurring decision, as follows.

"It should be apparent, however, that this first aspect of the enabling disclosure requirements of section 112 requires only that the adequacy of the teaching disclosure be measured as of the issue date of the patent. There is no sense in making an applicant publicly disclose any part of his invention, much less its very essence, before he has been assured that he will obtain the protection he is seeking in return for that disclosure." 434 F.2d 1390, 1394-1395.

Subsequent decisions have applied similar views. See, for example, *Feldman v. Aunstrip*, 517 F.2d 1351 (Court of Customs and Patent Appeals, 1975) (access during review can be restricted, and the depository is not required to be a public institution).

The nature of the biological deposit "requirement" is that it is not a requirement in the usual sense. Use of deposits is dictated by the need in

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particular circumstances to overcome what would otherwise be a deficiency in the patent description concerning the enablement of others to practice the patent. There is no requirement to deposit such material, per se.

Reinforcing this view, the courts have resisted arguments that biological materials should be required if their introduction is not forced by the necessity of proving the requirements for the patent. Use of biological deposits has been discussed, for example, in so-called "best mode" cases. At issue in such cases is whether, again under 35 U.S.C. § 112, an applicant in its application fully described the best mode contemplated by the inventor for carrying out his or her invention. Best mode has been held by the Court of Appeals for the Federal Circuit as having two components: (1) whether at the time of filing the inventor contemplated a best mode of practicing his or her invention and (2) whether his or her disclosure is adequate to enable one skilled in the art to practice that best mode. The applicant may not conceal a mode known to be better than that which is disclosed. *Amgen, Inc., v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir., 1991).

In *Amgen* it was argued that the plaintiffs should have made a biological deposit so that the public would have access to exactly the best mode contemplated by the inventor. Rejecting this point of view the court stated,

"When a biological sample required for the practice of an invention is obtained from nature, the invention may be incapable of being practiced without access to that organism. Hence the deposit is required in that case. On the other hand, when, as in this case here, the organism is created by insertion of generic material into a cell obtained from generally available sources, then all that is required is a description of the best mode and an adequate description of the means of carrying out the invention, not deposit of the cells. If the cells can be prepared without undue experimentation from known materials, based on the description in the patent specification, a deposit is not required." 922 F.2d at 1211.

Additional requirements applying to biotechnology and the practices and procedures for implementation of the final rule for deposits of biological materials for patent purposes are prescribed in the regulations at 37 C.F.R. § 1.801 – 1.809. These regulations, which became effective for all applications filed on or after January 1, 1990, generally reflected policy and practice—including those set out by judicial decision—existing prior to January 1, 1990. The development of these regulations was several years in the making—the advanced notice of proposed rulemaking was published on September 9, 1987; the notice of proposed rulemaking was published on October 6, 1988; and the final rule was published on August 22, 1989.

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PTO has also incorporated guidelines for biological deposits in its operating manuals. For example, PTO's *Manual of Patent Examining Procedure*, chapter 2400—Biotechnology provides guidance on the practices and procedures for implementation of the deposit rules. According to section 2402 of the manual,

"Every patent must contain a written description of the invention sufficient to enable a person skilled in the art to which the invention pertains to make and use the invention. Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112."

PTO's manual and 37 C.F.R. § 1.801 also define biological material as including material that is capable of self-replication, either directly or indirectly. Representative examples include bacteria, fungi, yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens, and seeds. Viruses, vectors, cell organelles, and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material.

Other countries also have had to deal with the issue of biological deposits. Accordingly, in an attempt to regulate biological deposits throughout the world, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty) was established in 1977 and became operational in 1981. Under this treaty, signatory countries—including the United States, which ratified the treaty in 1980—must recognize a biological deposit made in any depository approved by the World Intellectual Property Organization (WIPO). The treaty also established international standards for biological deposits and provided that a deposit in any WIPO-approved depository will be recognized as meeting the deposit requirements throughout the world. At present, there are 48 signatory nations to the Budapest Treaty and 31 depositories—known as International Depositary Authorities (IDA)—recognized by WIPO.

PTO has established procedures on what constitutes an acceptable depository in the United States. These are set out in PTO's manual and 37 C.F.R. § 1.803.

# Biotechnology and the U.S. Economy

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According to the Biotechnology Industry Organization (BIO),<sup>1</sup> biotechnology is often defined as “a combination of advances in our understanding of molecular and cellular biology, plant, animal and human genetics and how the human immune system fights disease.” BIO notes that the term actually covers a range of technologies, with the use of cells and biological molecules being the common link, and cites the following as examples:

- Monoclonal antibody technology involves the use of immune system cells that create antibodies that can be used for such purposes as distinguishing cancer cells from normal cells, locating environmental pollutants, and diagnosing infectious diseases.
- Cell culture technology involves the growing of cells outside of living organisms and is useful for such purposes as developing methods to kill insect pests without harming beneficial insects. Also, this technology may be used in the future to treat certain human diseases by replacing malfunctioning cells with normal cells grown outside the body.
- Biosensor technology combines biology and microelectronics by linking a biological component such as a cell or antibody with a transducer. This creates a biosensor that can be used in such applications as measuring the nutritional value and safety of food, locating and measuring environmental pollutants, and measuring vital blood components.
- Genetic modification technology, or recombinant DNA technology, allows the combining of genetic material from two different sources to create recombinant DNA. Genes may be combined at the molecular level through the use of genetic modification. The technology is beneficial in such applications as the creation of safer vaccines, the treatment of genetic diseases, the creation of enhanced biocontrol agents in agriculture, and the development of biodegradable plastics.
- Antisense technology uses small nucleic acids to block the genes responsible for making specific proteins and are being studied as ways to slow food spoilage, control viral diseases, inhibit inflammation, and

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<sup>1</sup>BIO includes more than 900 member companies. This organization, supported by the expertise and collective influence of its members, speaks on legislative, regulatory, and public policy issues affecting the biotechnology industry.

treat diseases such as asthma and cancer.

- Protein engineering technology is used in conjunction with genetic modification to improve existing proteins—usually enzymes—and to create proteins not found in nature. Unlike most industrial chemical catalysts, these biocatalysts dissolve in water and work best at neutral pH and comparatively low temperatures. Thus, they have proved useful in developing cleaner and energy-efficient production processes in the chemical, textile, pharmaceutical, pulp and paper, food and feed, metal and minerals, and energy industries.

These emerging technologies have made the biotechnology industry an important part of the U.S. and world economies. The companies entering the industry tend to be new, small, highly capitalized, and research-intensive. BIO cites the following statistics:

- There are 1,283 biotechnology companies in the United States. Approximately one third of these companies employ fewer than 50 employees, and more than two thirds employ fewer than 135 people.
- In 1998, the U.S. industry had a market capitalization—the amount of money invested in the industry—of \$97 billion.
- The U.S. industry employs more than 153,000 people in high-wage, high-value jobs.
- The U.S. industry is one of the most research-intensive industries in the world, spending \$9.9 billion in research and development in 1998. The top five biotechnology companies spent an average of \$121,400 per employee on research and development, compared with an average of \$30,600 per employee for the top pharmaceutical companies.

One of the most visible and important projects under way in the field of biotechnology is the Human Genome Project, which is identifying and mapping all the genes in the human body. The research from this project is expected to revolutionize the treatment of human illnesses and to result in a plethora of new medical products and processes.

Another area that has had an impact is the area of agricultural biotechnology. The industry has created disease resistant plants such as cucumbers, melons, pumpkins, and squash. Such innovations are important

given an ever-increasing population worldwide and scarce agricultural resources.

Biological products and processes can pay enormous dividends. However, they also come at a high cost. For example, bringing a new pharmaceutical to market can cost hundreds of millions of dollars, and there is no guarantee that the product will be successful. Before a company is willing to take the financial risk on a new product, it wants to ensure that it will have the exclusive rights to benefit from it. Thus, obtaining patent protection is extremely important for these companies. In a February 2000 article in *PTO TODAY Online*, Lila Feisee, a quality administrator in PTO's Technology Center 1600, which handles biotechnology patent applications, noted that patent protection also offers benefits to the public:

"Biotechnology patents allow for the dissemination of potentially valuable scientific information. The availability of the information disclosed in biotechnology patents enables others in the field of science to build on earlier discoveries. Not only can other researchers use the information in a patent, but by disclosing cutting edge scientific information, the patent system avoids expensive duplication of research efforts. It is only with the patenting of biotechnology that some companies, particularly small companies, can raise capital to bring beneficial products to the market place or fund further research. In addition, this capital provides jobs that represent an immediate public benefit independent of the technological benefits. Continuing employment opportunities represents a national resource for the future because it encourages the youth of today to become the scientists and inventors of tomorrow. Thus, the patent system not only fosters our society today, but also ensures our future ability to innovate and grow."

According to PTO, biotechnology patents are an increasing part of its workload. In calendar year 1999, PTO issued 16,882 patents that were examined by Technology Center 1600. This represented 10 percent of all patents issued by PTO during that year.

# Biological Deposits in the 31 International Depository Authorities Approved by the World Intellectual Property Organization

This appendix provides historical information on the number of biological deposits on hand at the 31 International Depository Authorities (IDA). In addition, historical information is provided on the number of samples of deposits furnished under rule 11 of the Regulations of the Budapest Treaty.

**Table 1: Deposits on Hand for the 31 IDAs, 1997 Through 1999**

International depository authority <sup>a</sup>	Country	At December 31		
		1997	1998	1999
Australian Government Analytical Laboratories	Australia	176	211	262
Belgian Coordinated Collections of Microorganisms	Belgium	167	198	237
National Bank for Industrial Microorganisms and Cell Cultures	Bulgaria	732	737	746
Bureau of Microbiology at Health Canada	Canada	<sup>a</sup>	0	2
China Center for Type Culture Collection	China	<sup>b, c</sup>	<sup>b</sup>	<sup>b</sup>
China General Microbiological Culture Collection Center	China	396	449	<sup>b</sup>
Czech Collection of Microorganisms	Czech Republic	56	62	65
Collection Nationale de Cultures de Micro-organismes	France	1,348	1,503	1,762
Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH	Germany	3,310	3,658	4,009
National Collection of Agricultural and Industrial Microorganisms	Hungary	193	199	211
Advanced Biotechnology Center	Italy	7	8	11
Collection of Industrial Yeasts	Italy	0	2	4
National Institute of Bioscience and Human-Technology	Japan	6,198	6,594	6,961
Microbial Strain Collection of Latvia	Latvia	2	4	9
Centraalbureau voor Schimmelcultures	Netherlands	742	763	789
Korean Cell Line Research Foundation	Republic of Korea	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>
Korean Collection for Type Cultures	Republic of Korea	417	563	719
Korean Culture Center of Microorganisms	Republic of Korea	121	143	180
All-Russian Scientific Centre of Antibiotics	Russian Federation	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>
Russian Collection of Microorganisms	Russian Federation	17	25	25
Russian National Collection of Industrial Microorganisms	Russian Federation	75	118	126
Culture Collection of Yeasts	Slovakia	0	0	0
Colección Española de Cultivos Tipo	Spain	149	176	230
Culture Collection of Algae and Protozoa	United Kingdom	3	3	4
European Collection of Cell Cultures	United Kingdom	1,048	1,153	1,205
International Mycological Institute	United Kingdom	127	158	168
National Collection of Type Cultures	United Kingdom	91	98	100
National Collection of Yeast Cultures	United Kingdom	39	39	45
National Collections of Industrial, Food and Marine Bacteria Ltd.	United Kingdom	1,174	1,260	1,292

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<b>International depository authority<sup>a</sup></b>	<b>Country</b>	<b>At December 31</b>		
		<b>1997</b>	<b>1998</b>	<b>1999</b>
Agricultural Research Service Culture Collection	United States	2,808	2,976	3,105
American Type Culture Collection	United States	13,922	15,635	17,356
<b>Total</b>		<b>33,318</b>	<b>36,735</b>	<b>39,623</b>

Note: According to WIPO's February 2000 publication, *Intellectual Property Laws and Treaties*, only 4 of the 31 approved IDAs accept deposits of seeds: the China Center for Type Culture Collection; the National Institute of Bioscience and Human-Technology in Japan; the National Collections of Industrial, Food and Marine Bacteria Ltd., in the United Kingdom; and the American Type Culture Collection.

<sup>a</sup>There were 31 approved IDAs in 1997, 1998, and 1999. However, during this period, one IDA—the National Collection of Food Bacteria in the United Kingdom—had its IDA status terminated on June 5, 1997. This IDA reported no deposits on hand at Dec. 31, 1997. A second IDA—the Bureau of Microbiology at Health Canada—received its sanctioning as an IDA on Nov. 30, 1998, and began official operations in mid-1999.

<sup>b</sup>WIPO has not reported 1999 data, nor did the IDA respond to our request for data.

<sup>c</sup>This IDA reported to WIPO that it had 1,076 deposits on hand at Dec. 31, 1996. WIPO has reported no information on this IDA since then.

Source: GAO-developed data based on contacts with individual IDAs and WIPO.

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**Table 2: Deposits on Hand for the 31 IDAs Grouped by Country, 1997 Through 1999**

<b>Country<sup>a</sup></b>	<b>Total number of deposits at December 31</b>					
	<b>1997</b>		<b>1998</b>		<b>1999</b>	
	<b>Number</b>	<b>Percentage of total</b>	<b>Number</b>	<b>Percentage of total</b>	<b>Number</b>	<b>Percentage of total</b>
Australia	176	0.53	211	0.57	262	0.66
Belgium	167	0.50	198	0.54	237	0.60
Bulgaria	732	2.20	737	2.01	746	1.88
Canada	<sup>a</sup>	<sup>a</sup>	0	0.00	2	0.01
China (2 IDAs)	396 <sup>b</sup>	1.19	449 <sup>b</sup>	1.22	<sup>b</sup>	<sup>b</sup>
Czech Republic	56	0.17	62	0.17	65	0.16
France	1,348	4.05	1,503	4.09	1,762	4.45
Germany	3,310	9.93	3,658	9.96	4,009	10.12
Hungary	193	0.58	199	0.54	211	0.53
Italy (2 IDAs)	7	0.02	10	0.03	15	0.04
Japan	6,198	18.60	6,594	17.95	6,961	17.57
Latvia	2	0.01	4	0.01	9	0.02
Netherlands	742	2.23	763	2.08	789	1.99

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Country <sup>a</sup>	Total number of deposits at December 31					
	1997		1998		1999	
	Number	Percentage of total	Number	Percentage of total	Number	Percentage of total
Republic of Korea (3 IDAs)	538 <sup>b</sup>	1.61	706 <sup>b</sup>	1.92	899 <sup>b</sup>	2.27
Russian Federation (3 IDAs)	92 <sup>b</sup>	0.28	143 <sup>b</sup>	0.39	151 <sup>b</sup>	0.38
Slovakia	0	0.00	0	0.00	0	0.00
Spain	149	0.45	176	0.48	230	0.58
United Kingdom (6 IDAs)	2,482	7.45	2,711	7.38	2,814	7.10
United States (2 IDAs)	16,730	50.21	18,611	50.66	20,461	51.64
<b>Total<sup>c</sup></b>	<b>33,318</b>	<b>100.01</b>	<b>36,735</b>	<b>100.00</b>	<b>39,623</b>	<b>100.00</b>

<sup>a</sup>There were 31 approved IDAs in 1997, 1998, and 1999. However, during this period, one IDA—the National Collection of Food Bacteria in the United Kingdom—had its IDA status terminated on June 5, 1997. This IDA reported no deposits on hand at Dec. 31, 1997. A second IDA—the Bureau of Microbiology at Health Canada—received its sanctioning as an IDA on Nov. 30, 1998, and began official operations in mid-1999.

<sup>b</sup>Data were unavailable or incomplete. One IDA in the Republic of Korea, two IDAs in China, and one IDA in the Russian Federation did not respond to our inquiries; WIPO had no 1999 statistics.

<sup>c</sup>Percentages may not equal 100.00 because of rounding.

Source: GAO-developed data based on contacts with individual IDAs and WIPO.

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**Table 3: Deposits on Hand for the 31 IDAs Grouped by Europe, United States, Japan, and All Other Countries, 1997 Through 1999**

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Grouping	Total number of deposits at December 31 <sup>a</sup>		
	1997	1998	1999
Europe <sup>b</sup>	8,205	9,019	9,856
United States	16,730	18,611	20,461
Japan	6,198	6,594	6,961
All other countries	2,185	2,511	2,345
<b>Total</b>	<b>33,318</b>	<b>36,735</b>	<b>39,623</b>

<sup>a</sup>Data are incomplete because one IDA in the Republic of Korea, two IDAs in China, and one IDA in the Russian Federation did not respond to our inquiries; WIPO had no 1999 statistics.

<sup>b</sup>Includes those countries that are member states of the European Patent Organization.

Source: GAO-developed data based on contacts with individual IDAs and WIPO.

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Under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, there are specific rules that were adopted as regulations under the treaty. Rule 11 establishes when a sample of a biological deposit can be furnished to interested industrial property offices, such as PTO or EPO (rule 11.1); to or with the authorization of the depositor (rule 11.2); and to parties legally entitled (rule 11.3). For example, under rule 11.1, PTO could request a sample be furnished to it if the application referring to the deposit had been filed with PTO. Under rule 11.2, a sample can be furnished to the depositor or any authorized party the depositor names. Under rule 11.3, a sample can be furnished to parties legally entitled as long as the industrial property office makes various certifications, such as the party has a right to a sample under the law governing patent procedure before that office.

Table 4 shows the extent to which samples of deposits have been provided under rule 11 of the Budapest Treaty. It is also important to note that the numbers in table 4 represent the number of times that samples have been provided. If a sample of one deposit was provided on 10 different occasions under rule 11.3, it would be counted as 10.

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**Table 4: Number of Samples Furnished by IDAs in 1999 Under Rule 11 of the Budapest Treaty**

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<b>International depositary authority</b>	<b>Country</b>	<b>Number of samples furnished in 1999 under</b>		
		<b>Rule 11.1</b>	<b>Rule 11.2</b>	<b>Rule 11.3</b>
Australian Government Analytical Laboratories	Australia	0	0	0
Belgian Coordinated Collections of Microorganisms	Belgium	0	8	0
National Bank for Industrial Microorganisms and Cell Cultures	Bulgaria	0	18	0
Bureau of Microbiology at Health Canada	Canada	0	0	0
China Center for Type Culture Collection	China	a	a	a
China General Microbiological Culture Collection Center	China	a	a	a
Czech Collection of Microorganisms	Czech Republic	a	a	a
Collection Nationale de Cultures de Micro-organismes	France	0	14	15
Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH	Germany	0	27	159
National Collection of Agricultural and Industrial Microorganisms	Hungary	0	2	6
Advanced Biotechnology Center	Italy	0	0	0
Collection of Industrial Yeasts	Italy	0	0	0
National Institute of Bioscience and Human-Technology	Japan	0	12	63
Microbial Strain Collection of Latvia	Latvia	0	0	0

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<b>International depositary authority</b>	<b>Country</b>	<b>Number of samples furnished in 1999 under</b>		
		<b>Rule 11.1</b>	<b>Rule 11.2</b>	<b>Rule 11.3</b>
Centraalbureau voor Schimmelcultures	Netherlands	0	2	4
Korean Cell Line Research Foundation	Republic of Korea	a	a	a
Korean Collection for Type Cultures	Republic of Korea	0	14	0
Korean Culture Center of Microorganisms	Republic of Korea	0	0	0
All-Russian Scientific Centre of Antibiotics	Russian Federation	a	a	a
Russian Collection of Microorganisms	Russian Federation	0	0	0
Russian National Collection of Industrial Microorganisms	Russian Federation	0	2	0
Culture Collection of Yeasts	Slovakia	0	0	0
Colección Española de Cultivos Tipo	Spain	0	2	0
Culture Collection of Algae and Protozoa	United Kingdom	0	0	0
European Collection of Cell Cultures	United Kingdom	0	5	1
International Mycological Institute	United Kingdom	0	6	0
National Collection of Type Cultures	United Kingdom	0	0	0
National Collection of Yeast Cultures	United Kingdom	0	0	0
National Collections of Industrial, Food and Marine Bacteria Ltd.	United Kingdom	0	3	11
Agricultural Research Service Culture Collection	United States	0	12	123
American Type Culture Collection	United States	b	b	7,000 <sup>b</sup>
<b>Total</b>		<b>0</b>	<b>127</b>	<b>7,382</b>

Notes: Under the Budapest Treaty, samples of deposits can be furnished to industrial property offices (rule 11.1), to the depositor or with the authorization of the depositor (rule 11.2), and to parties legally entitled (rule 11.3).

According to WIPO's February 2000 publication, *Intellectual Property Laws and Treaties*, only 4 of the 31 approved IDAs accept deposits of seeds: the China Center for Type Culture Collection; the National Institute of Bioscience and Human-Technology in Japan; the National Collections of Industrial, Food and Marine Bacteria Ltd. in the United Kingdom; and the American Type Culture Collection.

<sup>a</sup>WIPO has not reported 1999 data, and the IDA did not respond to our request for data.

<sup>b</sup>The 1999 number is an estimate from this IDA. This IDA could not distinguish how many deposits were provided under rule 11.1, rule 11.2, and rule 11.3. The IDA noted, however, that most of its distribution is under rule 11.3 since it complies with the U.S. rule on making the deposit available. This IDA also cautioned that these numbers represent the estimated number of vials (samples) and not necessarily the number of deposits.

Source: GAO-developed data based on contacts with individual IDAs and WIPO.

# Examination Time for Patents Issued From October Through December 1999 That Were Supported by Biological Deposits in U.S. IDAs

**Table 5: Average, Lowest, and Highest Examination Time for Seed and Other Patents Issued From October Through December 1999 That Were Supported by Biological Deposits in U.S. IDAs**

Description	Number of patents	Examination time in months		
		Average	Lowest	Highest
Seed patents	53	22.6	6.1	57.6
All other patents	255	39.9	8.4	113.1
<b>Total</b>	<b>308</b>	<b>36.9</b>	<b>6.1</b>	<b>113.1</b>

Note: Examination time, which PTO refers to as "pendency," is the period from the date when an application is filed until the date when a patent is issued or the application is abandoned.

Source: GAO analysis of data from PTO's patent database.

**Table 6: Ranges of Examination Time for Seed and Other Patents Issued From October Through December 1999 That Were Supported by Biological Deposits in U.S. IDAs**

Description	Number of patents examined					Total
	0-18 months	Greater than 18 to 24 months	Greater than 24 to 30 months	Greater than 30 to 36 months	More than 36 months	
Seed patents	17	23	3	7	3	53
All other patents	21	28	38	36	132	255
<b>Total</b>	<b>38</b>	<b>51</b>	<b>41</b>	<b>43</b>	<b>135</b>	<b>308</b>

Note: Examination time, which PTO refers to as "pendency," is the period from the date when an application is filed until the date when a patent is issued or the application is abandoned.

Source: GAO analysis of data from PTO's patent database.

# Comments From the United States Patent and Trademark Office

 **UNITED STATES PATENT and TRADEMARK OFFICE**

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND  
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
WWW.USPTO.GOV

Ms. Gary Jones OCT - 4 2000  
Associate Director, Energy, Resources,  
and Science Issues  
General Accounting Office  
Washington, DC 20548

Dear Ms. Jones:

Thank you for the opportunity to comment on the General Accounting Office's draft report entitled Intellectual Property: Deposits of Biological Materials in Support of Certain Patent Applications (GAO-01-49).

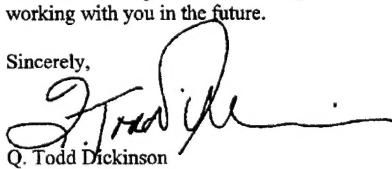
As the draft report accurately states, the Patent Act requires applicants to describe the claimed invention in sufficient detail to enable a person of skill in the art to practice the invention. Of course, this requirement governs all inventions from the simplest mechanical inventions to the most sophisticated biological inventions. As the report finds, very few applications actually take advantage of the opportunity to use a deposit to fulfill the disclosure requirement. The availability to submit a deposit enables American inventors to seek patent protection for their inventions where patent protection might not otherwise be available due to constraints imposed by merely using words to describe the invention. While this system is not unique to the United States, the ability to describe the invention using a deposit has contributed to the United States biotechnology industry being a world leader in that field.

In addition to instituting publication of patent applications, the American Inventors Protection Act of 1999 grants patent owners provisional patent rights, including a reasonable royalty, for the term between publication and the patent grant. Thus, with the availability of obtaining provisional rights, all applicants, including applicants who utilize the deposit system, have a strong incentive to disclose fully their invention at the time of pre-grant publication.

The opportunity for United States inventors to protect their valuable intellectual property is further enhanced by the efforts of the United States Patent and Trademark Office to encourage foreign countries to modernize their intellectual property systems so that United States inventors can continue to receive incentives to create new inventions. Continued progress on this front will further strengthen the intellectual property rights of United States inventors.

Once again, I thank you for the opportunity to participate with your staff on this project. They have been open to comments and suggestions made by various United States Patent and Trademark Office officials. The United States Patent and Trademark Office is pleased to continue the cooperation that our agencies have shared in the past, and I look forward to working with you in the future.

Sincerely,

  
Q. Todd Dickinson

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# GAO Contacts and Staff Acknowledgments

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## GAO Contacts

(Ms.) Gary L. Jones, (202) 512-3841  
John P. Hunt, Jr., (404) 679-1822

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## Acknowledgments

Kelly Fitzgerald, Frankie Fulton, Bert Japikse, and Paul Rhodes also made key contributions to this report.

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